

Remarks

Claims 1-9, 11-14 and 26-31 are pending in the application.

The Final Office Action mailed August 20, 2008, indicates that claims 1-14 and 26-31 are pending; however, claim 10 was previously cancelled.

Claims 1-9, 11-14 and 26-31 remain in the application for consideration.

Reconsideration and allowance of the claims in light of the following remarks are respectfully requested.

Claim Rejections - 35 USC § 103

I. Claims 1-3, 7-9, 12-14 and 26-31 Rejected Over Salama in View of Orban.

Claims 1-3, 7-9, 12-14, and 26-31 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Salama (U.S. Patent No. 5,306,226; hereinafter “Salama”) in view of Orban, III (U.S. Publ. No. 2005/0251155; hereinafter “Orban”).

The rejection is traversed for reasons of record, and as follows.

Salama is cited for its description of a flexible catheter body having a proximal end and a distal end, inflatable balloon, and drainage aperture. The Office Action provides that:

Salama discloses the claimed device, including a tissue approximating structure or means located on a proximal side of the drainage aperture, except for the tissue approximating structure or means being at the distal end of the catheter body . . . and the tissue approximating structure or means comprising a tine, prod, or needle, or multiple opposing tines.

(page 3). The Office Action indicates that Salama does not teach the feature of the tissue approximating structure at the distal end of the catheter (page 3). Orban is then cited for teaching “a tissue approximating structure . . . 110, 126 at the distal end of a catheter body having a catheter body wall at its distal end . . . compris[ing] a tine, prod, or needle, or multiple opposing tines and can be extended and retracted from the catheter body wall to contact tissue. . .” (page 3). The Office Action provides that it would have been obvious to one of ordinary skill in the art to provide the tissue approximating structure of Orban to Salama to arrive at the invention of claims 1-3, 7-9, 12-14 and 26-31 (page 3).

At page 2, paragraph 2, the Office action describes the Salama reference as showing “tissue approximating structure or means 36 on the catheter body capable of contacting bladder,

tissue of a perineal wall, urethral tissue, and combinations of these for holding severed tissue in contact for healing. . .” (Emphasis added.)

At page 5, paragraph 4, the Office action describes the Orban reference as showing “tissue approximating structure 110, 126” that “may be extended and retracted from a catheter body wall. . .” (Emphasis added.)

A. This Rejection is Based on Faulty Premises, in the form of Misunderstood Content of the Orban and Salama References

The rejection of claims 1-3, 7-9, 12-14, and 26-31 is legally insufficient and should be withdrawn.

The rejection relies on two faulty premises: (i) one faulty premise is that Orban describes or shows a device that includes tissue approximating structure that can be extended and retracted from a catheter body wall (page 5, paragraph 4); (ii) a second faulty premise is that Salama discloses tissue approximating structure at a distal end of the catheter body that is capable of contacting tissue selected from tissue of the bladder, tissue of a perineal wall, urethral tissue and combinations of these (pages 2 and 3).

(i) Orban does not disclose a tissue approximating structure that may be extended and retracted from a catheter body wall.

In assessing the content of the Orban device the Office action includes two mischaracterizations. The first is that Orban teaches tissue approximating structure that extends from a catheter body wall. The second is that the Orban tissue approximating structure can be retracted.

Orban describes and shows, in Fig. 7, an anastomosis apparatus having a plurality of fasteners 102 (in Figs. 1-6) radially disposed about a lumen 184 of an insertion sleeve 180. The fasteners 102 each include a first fastener portion 104 and a second fastener portion 106 (paragraph [0046]). With the apparatus being inserted transurethrally and positioned as shown in Fig. 7, insertion sleeve 180 is withdrawn in a proximal direction to expose sharpened proximal tip 118 on leg portion 110 of first fastener portion 104 (Fig. 8; paragraphs [0059], [0060]). The first fastener portion 104 is expelled out of an aperture at the distal end of the insertion sleeve. This does not amount to extending tissue approximating structure “from a catheter body wall”

as proposed by the Office action. To extend from a catheter body wall as recited in Applicants' claims, tissue approximating structure extends from a surface of a sidewall of the catheter, at a location along the length of Applicants' claimed catheter. This is clear from exemplary embodiments of tissue approximating structure found in Applicants' figures and described in Applicants' specification, e.g., at page 8 (lines 22-28) and at page 9 (lines 13-21). The claim language "extending tissue approximating structure "from a catheter body wall"" does not contemplate pushing (i.e., expelling) a device from an internal lumen out a distal end of a hollow insertion device as described by the Orban reference.

Referring back to the Orban reference, the apparatus is withdrawn further proximally to drive sharpened tip 118 through the wall of the bladder "B" (paragraph [0060]). Insertion sleeve 180 is then withdrawn further again to deploy sharpened tip 134 on anchoring leg portion 126 of the second fastener 106, which is driven through the wall of urethral stump "S" (paragraph [0061]). The remainder of the apparatus, other than the fastener, is then removed (paragraph [0062]), withdrawn from the body. This brings up the second mischaracterization of the Orban reference -- that Orban teaches a fastener that may be "retracted." To the contrary, once the Orban fastener is deployed there is no description of the fastener being retracted or in any other sense replaced to a non-deployed (e.g., a "retracted") position or pulled back into the insertion sleeve.

In an alternate embodiment, paragraphs [0064] and [0065] describe fasteners that include a "locking leg portion 206" and an "anchoring leg portion 208" (see Figs. 13A and 13B). In use, pulling a suture attached to the anchoring leg portion 208 allows a user to pull anchoring leg portion 208 away from locking leg portion 206, i.e., anchoring leg portion 208 is extended from the locking leg portion 206. However, neither the suture nor any other feature of the fastener allows a user to "retract" the anchoring leg portion 208 into the body wall of the insertion sleeve after the anchoring leg portion has been extended. This embodiment, like the others described by Orban, does not allow the user to retract tissue approximating structure back to a catheter body wall.

More generally, Orban describes using its apparatus for fastening two hollow body parts together, such as the bladder and a urethral stump (paragraphs [0003], [0013]). There is no discussion of a fastener being removed or retracted. The Orban reference relates to an operation of expelling the fastener from the open distal end of the insertion sleeve (not from a catheter

wall), followed by withdrawal and removal of the insertion sleeve from the patient while the fastener remains internal to the patient. Contrary to the express basis of rejection, the Orban reference does not contain any explicit or implicit description of a tissue approximating structure that can be extended and retracted from a catheter body wall. In fact, other than a conclusory statement of the presence of this feature in Orban (page 5, paragraph 4), the rejection does not address the “retracted from” feature. Because the rejection is based on a faulty understanding of the content of the Orban reference, the rejection should be withdrawn.

(ii) *Salama does not disclose a tissue approximating structure that is capable of contacting tissue selected from tissue of the bladder, perineal wall, urethra, or combinations of these.*

A second faulty premise of the Office action is that Salama discloses tissue approximating structure or means capable of contacting tissue selected from tissue of the bladder, tissue of a perineal wall, urethral tissue, and combinations of these (see page 2, paragraph 2).

At page 2, paragraph 2, the Office Action indicates that Salama discloses tissue approximating structure capable of contacting tissue of the bladder, tissue of a perineal wall, urethral tissue, and combinations of these for holding severed tissue in contact for healing. Elsewhere (e.g., at page 3, line 3), the Office action correctly states that the tissue approximating structure (in the form of collar 36) is not at the distal end of the catheter body.

Salama describes a device used to drain a bladder (col. 2, line 18). The device includes a urine tube 12 and a balloon 26 formed in part by sidewalls of the tube 12 (col. 2, lines 23-29). An anchoring collar means 36 is provided around the urine tube 12 and is placed at the outlet end of the urethra against the outside of a person's body (col. 2, lines 35-36 and 50-51). The collar 36, referred to in Final Office Action as the tissue approximating structure, is external to the body. Being located external to the body, the collar 36 is not at the distal end of the catheter and cannot contact tissue of the bladder, tissue of a perineal wall, urethral tissue and combinations of these. Therefore, a second faulty premise exists in the rejection.

B. If Combined, the Cited References Do Not Teach All Features of the Claims

The Salama and Orban references, if combined, do not lead one of skill to the subject matter of the rejected claims.

Claims 1, 9 and 26 require tissue approximating structure that “can be extended and retracted.” A feature of claims 1, 9, and 26 that is missing from the combination of references is tissue approximating structure that can be retracted.

The Office action indicates that combining structures from Orban with the device of Salama would result in the claimed subject matter. But as explained above Orban does not disclose any structure (e.g., tissue approximating structure) that can be retracted from a catheter body or insertion device, after being extended. Adding that same structure from the Orban device to the device of Salama would still not result in a device that includes tissue approximating structure that can be retracted. Prior art references must be taken on the whole. When considered as a whole, the cited references do not include tissue approximating structure that can be retracted, and neither would a device prepared by combining the references.

Another feature of claims 1, 9, and 26 that would not be a result of the proposed combination of Salama, modified in view of Orban, is tissue approximating structure capable of being extended and retracted from a catheter body wall. The Office Action identifies the anchoring leg portions 110, 126 on fastener 102 in Orban as being “tissue approximating structure,” and provides that the tissue approximating structure 110, 126 could be extended and retracted from the catheter body 180 wall (page 3). Again this premise is not correct. Modification of the Salama device to include structure from the Orban reference would not result in tissue approximating structure extending from a catheter body wall. Instead, the anchoring leg portions would be dispensed from (i.e., expelled from) an aperture at a distal end of an insertion sleeve. Again the proposed combination would not result in the subject matter of the claims, including tissue approximating structure that can be extended and retracted from a catheter body wall.

Multiple features of independent claims 1, 9, and 26 are neither described nor shown in the cited references and consequently would not be present in a device that results from combining the two reference. At a minimum, the references do not show tissue approximating structure as claimed: at a distal end and that can be retracted and extended from the catheter body

wall. Tissue approximating structure having this combination of features is not present in either cited reference, alone or in combination.

Furthermore, given these differences that remain upon combining the cited reference -- by removing structure from Orban and using that structure with the Salama device as proposed -- the Office action does not include any reasoned analysis as to why one of skill, in addition to combining the selected features from the cited references, would have made the **further changes** to the Orban structures that would be necessary to produce subject matter of the pending claims. As a specific example, there is no explanation of why one of skill would have **further modified** the cited prior art structures to produce tissue approximating structure capable of being **retracted from a catheter body wall**. The Office action states:

It would have been obvious . . . to provide tissue approximating structure or means comprising multiple opposing tines at the distal end of a catheter body, as taught by Orban, to Salama in order to facilitate the approximation of tissue portions . . . making the process more efficient and simple to use.

This conclusory statement does not indicate how or why one of skill would have further modified the structure of Orban, when supposedly placing that structure on the Salama device, in a manner to result in tissue approximating structure as claimed: at a distal end of a catheter body, that can be retracted and extended from the catheter body wall.

The stated general motivation does not explain why one of skill would have been guided or motivated to modify the structure of Orban (the “fastener”) from one that is expelled from an aperture at a distal end of an insertion sleeve, into tissue approximating structure that can be extended from a catheter body wall, and that is capable of being retracted. That modification of the Orban “fastener” structure is necessary produce subject matter of the present claims, and is not shown or suggested by the cited references. That modification would alter the fundamental structure, design, and utility of the Orban structure. The Orban device requires two separate pieces: 1) a fastener that is put into place by, 2) an insertion sleeve that is separate from the fastener. The fastener and insertion sleeves are separate pieces; they are required to be separate because they perform as described, by the insertion sleeve placing the fastener in a patient and then being removed, leaving the fastener in the patient. The device of the rejected claims, in a novel manner, places tissue approximating structure at a location on a catheter body, inseparable from the catheter body, not to be delivered by the catheter body but to be used with the catheter

body as a single device; tissue approximating structure can be extended and retracted from the catheter body wall, not merely placed at tissue by being expelled from an end of the device.

The rejection does not indicate how or why one of skill would have been motivated or guided to make the fundamental changes in the structure of the Orban reference that would have been **still necessary** to arrive at the claimed subject matter, after the Orban structure would have been added to the Salama device. The proposed rationale, the need for efficiency and simplicity, is a basic goal desired for most medical devices. Being generally applicable to medical devices, these abstract “reasons” would not have led one of skill, starting from the cited art, which is demonstrably different, to the novel combination of features of the rejected claims. Simplicity and efficiency are advantages associated with the claimed structures but they are mere abstractions, too vague to have performed the requisite function of guiding a skilled person in the novel direction identified by the present inventors. Instead, the subject matter of the pending claims is based on insight and creativity possessed by the inventors and not shown or suggested by the cited prior art.

C. The Cited References Teach Away from the Rejected Claims

Finally, both Orban and Salama teach away from multiple features that are expressly found in the rejected claims.

Orban teaches a system of two separate components that include 1) an insertion sleeve and 2) a separate fastener. The insertion sleeve can be used to place a “fastener” at tissue. After placement of the fastener, the insertion sleeve is removed and the fastener remains. The reason that the two components are separate is because of their function. The system functions to allow placement of the fastener and removal of the insertion sleeve, so these components must be separable; the components would not function as required if the fastener were not separable from the inserter device. In this way the Orban reference teaches away from the subject matter of the present claims, which requires tissue approximating structure that functions as a part of the catheter body, e.g., that that can be extended and retracted from the catheter body. As opposed to the Orban system, the rejected claims relate to a device that allows tissue to be held together while the catheter body is in place; the tissue approximating structure functions to hold tissue for healing and the catheter body functions to provide drainage during healing. After healing, the

tissue approximating structure is retracted into the catheter body and the catheter body is removed from the patient.

Additionally, the Orban reference teaches away from tissue approximating structure capable of being extended and retracted from a catheter body wall. The Orban reference expels a fastener from an aperture at a distal end of an “insertion sleeve.” The fastener would not be capable of being dispensed from a catheter body wall and still have a structure and function that is overall consistent with the Orban reference.

Additionally, certain of Applicants’ dependent claims recite tissue approximating structure capable of contacting tissue selected from tissue of a bladder, tissue of a perineal wall, urethral tissue and combinations of these (claim 2, for example). Salama teaches away from claims that include this feature because the Salama device is located external to the body of the patient. Because collar 36 is outside the body, the collar cannot contact tissue of the bladder, perineal wall, or urethra.

II. Claims 4-6 and 11 Rejected Over Salama and Orban and Further in View of Biggs

Claims 4-6 and 11 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Salama and Orban, as applied to claims 1, 3, and 9 above, and further in view of Biggs et al. (U.S. Patent No. 6,599,311).

These rejections are traversed in the same fashion as applied above with respect to the rejection of claims 1-3, 7-9, 12-14 and 26-31.

The additional reference, Biggs et al., does not remedy the shortcomings of Salama and Orban with respect to the features of independent claims 1 and 9.

Overall, the rejection of claims 4-6 and 11 under 35 U.S.C. 103(a) as being unpatentable over Salama and Orban as applied to claims 1, 3 and 9, and further in view of Biggs et al. is legally insufficient. Accordingly, Applicants respectfully request withdrawal of the rejection and allowance of the subject claims.

In view of the present remarks, allowance of the pending claims is respectfully requested.

The Examiner is invited to contact the undersigned, at the Examiner's convenience, should the Examiner have any questions regarding this communication or the present patent application.

Respectfully Submitted,

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